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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,671	06/25/2003	James Roy Maxwell	1391/1555	4734

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EXAMINER	
DAVIS, RUTH A	
ART UNIT	PAPER NUMBER
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/606,671	MAXWELL ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) *42-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41 and 71-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Request for Continued Examination, amendment, response, and affidavit filed on October 23, 2006 and the IDS filed on September 25, 2006 have been received and entered into the case. Claims 1 – 74 are pending; claims 42 – 70 are withdrawn from consideration; claims 1 – 41 and 71 – 74 have been considered on the merits. All arguments, the declaration and IDS have been fully considered.

Claim Objections

Claim objections have been withdrawn due to amendment.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 – 41 and 71 – 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification as originally filed, in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a pullulan free edible film comprising an amount of magnolia Bark extract such that the composition provides a concentration of greater than about 3.0 micrograms per milliliter of saliva in the oral cavity of a user. However, the specification fails to teach or disclose such an amount of what appears to be MBE per ml saliva. The specification does teach the MBE has a MIC of particular amounts (spec, page 4), however the specification does not teach a film that provides a particular concentration per ml of saliva. This is a new matter rejection.

Applicant argues that no undue experimentation is required for the claimed invention and that the specification teaches amounts of MBE to be delivered to the oral cavity.

However, these arguments are not persuasive because the rejection above is not directed to lack of enablement, but to a recitation of new matter in the claims. The amounts of MBE in the strip, delivered to the oral cavity are supported by the specification as argued, however the claims recite a particular amount of MBE per ml of saliva which is not supported by the specification as originally filed. The specification does not teach or disclose an amount of MBE per ml of saliva as presently claimed. Thus the claims stand rejected.

3. Rejections under rejected under 35 U.S.C. 112, second paragraph, are withdrawn due to amendment.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1 – 41 and 71 – 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barkalow (WO 02/43657 A2) in view of Nanba and/or Scherl.

Applicant claims a pullulan free edible film composition comprising an effective amount of a film forming agent and an effective amount of a MBE such that the composition provides greater than about 3.0 ug/ml saliva in the oral cavity of the user. The film forming agent comprises a mixture of maltodextrin, filler and hydrocolloid; the maltodextrin comprises 5 – 60% or 20 – 40% of the film; the hydrocolloid comprises 10 – 50% or 20 – 30% of the film; the filler comprises 5 – 30% or 15 – 25% of the film. The hydrocolloid is selected from natural gums, biosynthetic gums, natural seaweeds, natural plant extrudates, natural fiber extracts,

gelatin, processed starch, cellulosic materials, alginates, pectin and combinations thereof; natural seed gum, guar gum, locust gum, tara gum, gum Arabic, ghatti gum, agar gum and xanthum gum; sodium alginate or calcium alginate; or a carrageenan. The filler is a food grade bulk filler selected from microcrystalline cellulose, cellulose polymers, magnesium carbonate, calcium carbonate, ground limestone, silicates, clay, talc, titanium dioxide, calcium phosphates and combinations thereof; wood; magnesium or aluminum silicates or combinations thereof; mono-calcium phosphate, di-calcium phosphate, tri-calcium phosphate or combinations thereof. The magnolia bark extract is about 1 – 10%, 8% 5% of the film; and comprises magnolol and/or honokiol. The composition further comprises an effective amount of a medicament that is that is an oral cleansing, breath freshening agent selected from pH control agents, inorganic components for tartar/caries control, breath freshening agents, anti-plaque agents, anti-gingivitis agents, saliva stimulating agents, pharmaceutical agents, nutraceutical agents, vitamins, mineral and combinations thereof. Specifically, the medicament is urea; phosphates or fluorides; zinc gluconate; chlorhexidene, CPC, triclosan or combinations thereof; a food acid selected from citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, tartaric acids and combinations thereof. The composition further comprising a softening agent at about 0 – 20% or 2 – 10%; and is selected from sorbitol, glycerin, PEG, PG, hydrogenated starch hydrosylates, corn syrup and combinations thereof. The composition further comprises a coloring agent; a flavoring agent at at 0.1 – 20% or 10 – 15%. The flavoring is selected from essential oils, synthetic flavors, fruit essences, anise, flavor oils with germ killing properties and combinations thereof; oils of citrus, peppermint, spearmint, mint, clove, wintergreen and combinations thereof; menthol, eucalyptus, thymol and combinations thereof. The composition further comprises an effective amount of

emulsifier; that is selected from lecithin, (c10-C18) fatty acids, monoglycerides, diacylglycerides, ox bile extract, polyglycol esters, polyethylene sorbitan esters, propylene glycol, sorbitain monopalmitate, sorbitan monosteerate, sorbitan triesterate, enzyme modified lecithin, hydroxylated lecithins and combinations thereof. Applicant additionally claims a pullulan free edible film comprising an effective amount of a film forming agent and an effective amount of MBE for reducing bacterial concentrations of P. gingivalis and F. nucleatum in the oral cavity of the user, such that the composition provides a concentration of MBE greater than about 3.0 ug/ml saliva. The composition provides greater than 3.9ug/ml saliva against P. gingivalis; 3.9 or 7.8 um/ml saliva against F. nucleatum.

Barklalow teaches a pullulan free edible film comprising a film forming agent, filler, plasticizing agent (softener), medicaments and additives for treating halitosis, plaque, or gingivitis (abstract). The film forming agent is present at 10 – 90% and is selected from cellulose ether, modified starches, natural gums, polymers, hydrocolloids, seaweed, land plant extrudates and combinations thereof (p.2), gum arabic, guar gum, carageenan gum, ghatti, xanthum gum, locust gum and combinations thereof (p.6), alginates and/or pectin (p.7). The filler is present at 10 – 90% and is selected from magnesium carbonate, calcium carbonate, calcium phosphate, magnesium and calcium silicates, limestone, clay, talc, titanium dioxide, microcrystalline cellulose, cellulose polymers, wood and combinations thereof (p.7). The plasticizing agent is present at about 0 – 20 or 2 – 8% and is selected from sorbitola, glycerin, polyethylene glycol, propylene glycol, hydrogenated starch hydrolysates, corn syrup and combinations thereof (p.7-8). The film further comprises a medicament selected from pH control agents, oral care agents, breath freshening agents, pharmaceutical agents, nutraceutical

agents, saliva stimulating agents, vitamins, mineral and combinations thereof, urea, caries control agents, phosphates, fluorides, chlorohexidene, CPC, triclosan, citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, tartaric acids and combinations thereof, zinc gluconate, oils of citrus, peppermint, spearmint, mint, clove, wintergreen, anise and menthol (p.8-9). Other additives include coloring agents, flavoring agents and emulsifiers (p.9). The flavors are present at 0.1 – 20% or 10 – 15% and may be selected from essential oils, synthetic flavors, flavors derived from fruit (p.9). Emulsifiers may include hydrogenated vegetable oils (p.10) and/or lecithin (examples 1-12). The compositions further comprise maltodextrin (examples 1 – 4).

Barkalow does not teach the film wherein the medicament is magnolia bark extract; wherein the magnolia bark extract comprises magnolol and/or honokiol; wherein the claimed amounts of magnolia bark extract are present, or wherein the film provides the claimed amounts to the oral cavity against the claimed bacteria. However Barkalow does teach the medicaments may be agents for preventing dental caries, anti-plague agents, and/or anti-gingivitis agents. At the time of the claimed invention, magnolia bark extracts were known to have these properties. In support, Nanba teaches extracts of magnolia bark that contain magnolol and honokiol, which are effective for preventing and inhibiting dental caries (abstract) and Scherl teaches a composition comprising magnolia extract that contains honokiol and magnolol, which is an effective anti-plaque and anti-gingivitis agent (abstract). Scherl further teaches the compositions are effective against F. nucleatum (see examples). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Nanba and/or Scherl, to include magnolia bark extract in the film of Barkalow, since it was a well known agent for preventing dental caries, plague and gingivitis, as evidenced by Nanba and Scherl. In addition, since such

medicaments are recognized result effective variables, it would have been obvious to one of ordinary skill in the art to optimize the amounts of magnolia bark extract in the film of Barkalow (thus also the concentration administered), with a reasonable expectation for successfully obtaining the effective edible film of Barkalow.

Barkalow does not teach each of the claimed ingredients in the claimed amounts. However, since such ingredients and additives are recognized result effective variables, it would have been obvious to one of ordinary skill in the art to optimize the amounts of film forming agents in the film of Barkalow, with a reasonable expectation for successfully obtaining the effective edible film of Barkalow.

Finally, although the references do not identify the compositions are effective against P. gingivalis, they each teach the compositions are useful for treating gingivitis. Since it was known in the art that P. gingivalis is the most common organism strongly associated with gingivitis, one in the art would have recognized that the instant compositions would be effective against P. gingivalis.

Response to Arguments

Applicant argues that the art recognizes pullulan as a required ingredient in edible films; that the amount of MBE in Scherl is 14 times higher than claims amounts; that there is an unexpected result in that such small amounts of MBE can be used and still be effective. Applicant provide an affidavit stating the same. Applicant further argues that there must be a reasonable expectation for success and a motivation for lowering the amount.

However, these arguments fail to persuade because Barkalow clearly teaches edible films without requiring pullulan. As such, the art clearly teaches edible films without the presence of pullulan. In addition, while Scherl may teach higher amounts of MBE, the claims recite an amount greater than 3.0ug. Thus, the teachings of Scherl are great than 3.0ug MBE. While it is appreciated that applicants have provided an affidavit stating the surprising effects of such small amounts of MBE, the claims are not commensurate in scope with such evidence. Moreover, the claims are not limited to consist of only the small amount as presented in the arguments and affidavit, but may comprise at least the argued amount.

Regarding applicant's assertion that there is not a reasonable expectation of success, it is reiterated that Barkalow teaches a pullulan free, edible film with medicaments and the supporting references both teach MBE are effective for treating dental carries, plaque and gingivitis. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the MBE in the film of Barkalow with a reasonable expectation for successfully obtaining the effective edible film of Barkalow.

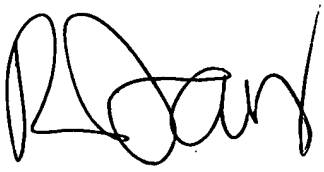
The claims are rejected for these reasons and those stated in the rejections above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ruth A. Davis
Primary Examiner
Art Unit 1651



January 5, 2007